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10/803,180	03/18/2004	Michele Cargill	CL001511	6182

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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,180	CARGILL ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-26* is/are pending in the application.

4a) Of the above claim(s) *8-22,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,23 and 24* is/are rejected.

7)☒ Claim(s) *1-4,6,7,23 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 and 6-26 are pending.
Claim 5 is cancelled.
Claims 8-22, 25 and 26 are withdrawn.
Claims 1-4, 6, 7, 23 and 24 are examined on the merits.

Election/Restrictions

1. Applicant's election with traverse of the invention of Group I (methods for identifying an individual who has an altered risk for developing an autoimmune disease using nucleic acid based methods to detect SNPs) in the reply filed on 09/26/2006 is acknowledged. Applicants' further elections of the particular disease rheumatoid arthritis (RA) and the polymorphism of hCV163035 (which is also disclosed in the specification as rs2276864 and SEQ ID NO: 5502) are also acknowledged.

The traversal is on the ground(s) that MPEP §803.04 states that 'normally ten sequences constitute a reasonable number for examination purposes'. This is not found persuasive because the different nucleic acid sequences disclosed as the different SEQ ID NOs of the instant application are not in fact disclosed as being used together nor do the claimed methods require that the sequences are used together (e.g. simultaneous analysis of the different polymorphic sequences). Regarding MPEP § 803.04, since the addition of these guidelines to the MPEP the biological sequence databases required to be searched for the examination of any sequence have grown tremendously and thus the Technology Center no longer routinely examines and searches more than one independent biological sequence. Furthermore, as set for the in the Requirement for Restriction of 07/26/2006 (page 7), the examiner maintains that a

search of any one specific sequence would be coextensive with a search of any other different sequence because, from a prior art perspective, a reference against one sequence would not be expected to be a reference against any other sequence. Additionally each sequence requires its own search of the art with regard to issues of enablement under 35 USC 112 1st ¶.

Regarding the election of a single autoimmune disease from those recited in claims 7 and 8, applicant argues that claim 8 is a Markush-type claim (beginning Remarks page 8). The examiner maintains that the different methods for identifying an altered risk for any different autoimmune disease are patentably distinct, and it would be a burdensome to search each of the 16 different recited diseases of claims 7 and 8. However, if the generic claim (claim 1) is found allowable (e.g. free of rejections under 35 USC 102, 103, and 112), then the additional species recited in claim 8 will be rejoined with the elected invention and each of these species will be examined.

It is noted that the elected SEQ ID NO: 5502 is identical to SEQ ID NO: 1658 of the instant application. As such, the restriction requirement between these two sequences is WITHDRAWN.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-22, 25 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/26/2006.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement; see for example pages 1-8 of the instant specification and the references cited therein. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper". Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The disclosure is objected to because of the following informalities: In the sequence listing, it is appropriate to identify each unique sequence with a unique 'SEQ ID NO:' sequence identifier. The sequence listing of the instant application indicates two sequences identified by SEQ ID NO: 1658 and SEQ ID NO: 5502, however the nucleotide sequences associated with SEQ ID NO: 1658 and SEQ ID NO: 5502 are identical.

Appropriate correction is required.

Claim Objections

4. Claims 1-4, 6, 7, 23, and 24 are objected to because they specifically recite non-elected subject matter. Claims 1-4, 6, 7, 23, and 24 require the analysis of the non-

elected SEQ ID NOs. Applicant has elected for the examination of the claims in so far as they require SEQ ID NO: 5502, which contains the SNP identified as hCV163035 and rs2276864. Prior to allowance of these claims, the non-elected subject matter will be required to be deleted from the claims.

Claim Rejections - 35 USC § 112 2nd¶ - Indefiniteness

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4, 6, 7, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6, 7, 23 and 24 are unclear over recitation of the phrase 'a single nucleotide polymorphism as represented by a nucleotide sequence selected from the group consisting of SEQ ID NO: 5502' (as recited in claims 1 and 23, as consonant with the election) with regard to detecting a SNP. SEQ ID NO: 5502 is not itself a SNP, but rather a nucleotide sequence comprising a particular position that is polymorphic in the human population, and as such it is unclear as to what is intended to be meant by a SNP represented by a sequence (i.e., is the method one which detects any T or C nucleotide, one which detects the occurrence of SEQ ID NO: 5502 or one which detects a sequence with some particualr level of similarity to SEQ ID NO: 5502). Further, it is unclear how the phrase 'as represented by' relates the SEQ ID NO: 5502 to the detected SNP. Does the claimed method require the detection of the nucleotide content

in a polymorphic position of SEQ ID NO: 5502, or is some other association such as linkage disequilibrium sufficient for SEQ ID NO: 5502 to represent any particular SNP.

Claims 23 and 24 are unclear over recitation of the phrase 'hybridizes to a SNP' in claim 23. A SNP is a variable position within a nucleic acid sequence. Thus it is not clear if applicant intends for the method to include hybridization to a particular specific allelic variant of the claimed sequence, to all possible variants of the sequence, or to just the SNP position. For example, in the case where a SNP position can be either a C or a T, would a single G nucleotide be considered a reagent that 'hybridizes specifically to a SNP'.

Claim Rejections - 35 USC § 112 1st - Written Description

7. Claims 1-4, 6, and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

> Applicant is referred to the guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-111 (also available at www.uspto.gov <http://www.uspto.gov>).

The rejected claims are drawn to methods comprising detecting a single nucleotide polymorphism (SNP) as represented by SEQ ID NO: 5502, wherein the presence of the SNP is correlated with an altered risk for autoimmune disease. The claims are thus broadly drawn to methods comprising the detection of a variety of

nucleic acids, including any SNP variant of SEQ ID NO: 5502 that is associated with an altered risk for autoimmune disease.

When the claims are analyzed in light of the specification, the instant invention encompasses methods comprising the detection of a large number of nucleic acid sequences. The claims are drawn to a plurality of nucleic acids that encompass an extremely large genus of SNP variants of SEQ ID NO: 5502 with any nucleotide content (A or G or C or T) at any position within the 201 nucleotide length of SEQ ID NO: 5502, as well as deletions and insertions (specification page 6 lines 12-19). Thus the claims encompass at least the detection of any of 1,632,240,801 (i.e. 201^4) different nucleic acids wherein the nucleic acid sequence is correlated with any altered risk for autoimmune disease. Nucleic acids of such a large genus have not been taught by the specification.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. The instant specification provides the sequence of SEQ ID NO: 5502 as well as the identical sequence in SEQ ID NO: 1658 wherein the nucleotide at position 101 is indicated to be polymorphic and can be either an A or a G, and provides an analysis indicating that the presence of an A is correlated with an decreased risk of developing RF+ RA. The specification does not provide any other polymorphic positions of SEQ ID NO: 5502 that would result in any other alteration in the sequence disclosed as SEQ ID NO: 5502 that is correlated with any altered risk for any autoimmune disease.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the specification does not provide any characteristics that would allow the identification of the broadly claimed SNPs in SEQ ID NO: 5502 other than the A/G at position 101 which would allow for the identification of an individual who has an altered risk for developing an autoimmune disease wherein the autoimmune disease is RF+ RA. Neither the instant specification nor the prior art provide guidance as to how one would a priori identify any of the broadly claimed SNP of SEQ ID NO: 5502 that is indicative of risk of developing an autoimmune disease.

Applicants' attention is directed to the decision in In re Shokal, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In the instant application, because of the lack of any analysis regarding SNPs of SEQ ID NO: 5502 other than the polymorphic content at position 101, one of skill in the art cannot envision the detailed chemical structure of the nucleic acids encompassed by the claimed methods, regardless of the complexity or simplicity of the method of

isolation. Adequate written description requires more than a mere statement that such nucleic acids are part of the invention and reference to a potential method for identification. The particular nucleic acids are themselves required.

In conclusion, the limited information provided regarding the nucleic acids of the claimed methods is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a method for identification of an individual with an altered risk for developing an autoimmune disease by determining the presence of a SNP in SEQ ID NO: 5502other than methods using the A/G SNP at position 101 of SEQ ID NO: 5502.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

Claim Rejections - 35 USC § 112 1st¶ - Scope of Enablement

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4, 6, 7, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification:

While being enabling for, with regard to claims 1-4, 6, and 7:

> A method for identifying a human individual who has a decreased risk for developing positive autoantibody rheumatoid factor (RF+) rheumatoid arthritis (RA) comprising:

obtaining a biological sample from said individual wherein the biological sample comprises nucleic acids;

detecting the nucleotide content at position 101 of SEQ ID NO: 5502 in said nucleic acids;

wherein, detecting the nucleotide A at position 101 of SEQ ID NO: 5502 identifies the individual as having a decreased risk for developing RF+ RA.

And being enabling for, with regards to claims 23 and 24:

A method of detecting a SNP in a nucleic acid molecule, the method comprising contacting a test sample with a reagent which specifically hybridizes to a SNP in SEQ ID NO: 5502 wherein the SNP is either an A or a G at position 101 of SEQ ID NO: 5502.

The does not reasonably provide enablement for methods comprising the identification of any non-human subjects, or identification methods comprising correlating any other nucleotide content at any other position in SEQ ID NO: 5502 with any autoimmune disease, or associating any other nucleotide content with any autoimmune disease other than RF+ RA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection of claims 23 and 24 is based on the purpose of such methods in the identification of SNPs that are associated with autoimmune disease, as asserted on pages 8 and 9 of the instant specification.

Nature of the invention and breadth of the claims

The claims of the instant application are drawn to methods for identifying an individual who has an altered risk for developing an autoimmune disease.

The claims encompass the analysis of any organism, including any non-human organism.

The claims encompass detecting any SNP broadly claimed as 'represented by a nucleotide sequence selected from the group consisting of 5502' (consonant with the election), where the language of the claims includes the detection of any nucleotide at any position in any sequence 'represented by' SEQ ID NO: 5502.

The claims broadly encompass methods in which detection of a SNP is correlated with any altered risk (i.e. increased risk or decreased risk) of any autoimmune disease.

The nature of the inventions requires knowledge of an association between broadly claimed nucleic acid content and altered risk of having an autoimmune disease.

Direction provided by the specification and working example

The instant specification teaches that an association study of a SNP and a specific disorder involves determining the presence or frequency of the SNP allele in biological samples from individuals with the disorder (i.e. cases) of interest and comparing the information to that of control individuals who do not have the disorder (p.7 ln.28 – p.8 ln.4).

The instant specification provides an example of an association study of the polymorphic content at position 101 of SEQ ID NO: 5502, which may be either an A or a G, and is also identified as hCV163035 and known in the art as rs2276864. The specification teaches that the frequency of the particular allele was analyzed in two (p.120 ln.26 – p.121 ln.11) patient populations: a Discovery Set (475 unrelated cases

and 475 controls who were RF+); and a Replication Set (840 cases from 463 families and 926 controls). The specification further indicates that the Replication set was analyzed in totality (i.e. an 'all' stratum) after stratification of the subjects into an RF+ stratum (p.12; p.121 ln.28).

The specification teaches the specific association of the A allele (i.e. an A nucleotide a position 101 of SEQ ID NO: 5502) with a decreased risk of RA as the A allele is found at a significantly higher frequency in control samples in the Discovery Set and the Replication Set (Table 6;). It is noted that Table 6 designates the 'T' allele as associated with the decreased risk of RA, and the specification indicates that nucleotide content may be described as the reverse complement of the nucleotide content at the position (e.g. p.20, lns.25-30), thus the T allele of the reverse complement of SEQ ID NO: 5502 is the A allele of SEQ ID NO: 5502. The analysis of the Discovery Set is an analysis of RF+ RA, because as stated in the specification all cases of the Discovery Set were RF+ (p.120 ln.29). While the instant specification provides that the A allele is indicative of a decreased risk for RA in the Replication Set in the 'All' Stratum, the specification provides no indication as to how many of the cases in the Replication Set were either RF+ or RF- (i.e. while the specification indicates that the Replication Set had 840 patients, it is not known if there were enough of both RF+ and RF- individuals to make data regarding the 'All' stratum significant for both RF+ and RF-). Thus it is not possible to determine from the data of Table 6 indicating a significant relationship between the A allele of SEQ ID NO: 5502 and decreased risk of RA is in fact significant within the RF- population of cases under analysis. Thus while the data of specification

teaches an association of the A allele with decreased risk of RF+ RA, it is not clear from the specification if the A allele is specifically associated in the same way, or in a significant fashion, with RF- RA.

The instant specification asserts that since autoimmune diseases share certain similar features that may be due to common genetic factors, SNPs associated with RA may also be used as makers for other autoimmune diseases (p.9, ln.1; p.121, ln.28). However, the instant specification provides no indication of any particular level of association of any SNP with any phenotype other than RA.

The instant specification provides only examples of the analysis of humans.

The instant specification provides only the association analysis of either an A or a G at position 101 of SEQ ID NO: 5502 (as consonant with the Election), and does not provide any analysis of any other polymorphic content at any other position of SEQ ID NO: 5502.

State of the art, level of skill in the art, and level of unpredictability

While the state of the art and level of skill in the art with regard to the detection of a polymorphism in a known gene sequence is high, the level of unpredictability in associating any particular polymorphism with a phenotype is even higher. The level of unpredictability is demonstrated by the prior art, the post filing art, and the instant specification.

The prior art does not teach any association between any polymorphism in SEQ ID NO: 5502 and altered risk for developing any autoimmune disease. And because the claims encompass the detection of any SNP 'as represented by a nucleotide

sequence selected from the group consisting of SEQ ID NO: 5502', it is relevant to point out the unpredictability in associating any particular SNP with a particular phenotypic trait. For example, Hacker et al teaches that they were unable to confirm an association between a gene mutation and ulcerative colitis in a case where prior studies suggested such a relationship would exist since the relationship had been identified in a different population (Gut, 1997, Vol. 40, pages 623-627).

While the claims of the instant application are broad enough to encompass analysis of any organism, the instant specification provides evidence only of a statistically significant association between the nucleotide content at position 101 of SEQ ID NO: 5502, which is a human gene sequence, and RF+ RA in humans. It is unpredictable as to whether or not a sequence comprising SEQ ID NO: 5502 exists in any non-human organisms, and whether or not detection of a polymorphism in such a sequence in any other organism would be predictive of risk of developing any autoimmune disease.

Because the claims encompass identifying an altered risk of any form of RA (e.g. RA that is either RF+ or RF-), it is relevant to point out that the instant specification does not particularly indicate an association between the nucleotide content of position 101 of SEQ ID NO: 5502 and RF- RA. It is relevant to point out that the post filing art indicates a difference in the genetics underlying the RF+ versus the RF- forms of RA. For example, the post filing art of Harrison et al (2006) indicates that an allele of the SNP identified as rs2476601 is associated with RF+ RA but not associated with RF- RA (p.1010, left col., 1st ¶ of Results; Table 1; p.1011, left col., Key messages box).

Similarly, Lee et al (2005) teach that the same rs2476601 polymorphism is not associated with RF- RA (p.129 – Abstract; p.130, right col., lns.5-15; Table 1), and Begovich et al (2004) indicate that an allele of rs2476601 (p.331, left col., lns.14-15) is not significantly associated with the RF- form of RA (Table 3; p.333, right col., lns.9-13). In an analysis of the association of an FcγRIIIa polymorphism with RF+ and RF- RA, Chen et al (2006) reports a significant skewing of the observed distribution of the 'F' allele with the RF- form of the disease (p.10.– Summary; Table 1; p.12, right col., lns.4-7). Given the lack of any RF- versus RF+ stratification of the population examined by the examples of the instant specification, and the teachings in the art with regard to the genetic differences of the RF+ versus the RF- forms of RA, it is unpredictable as to whether or not the nucleotide content of position 101 of SEQ ID NO: 5502 is reliably associated with increased risk of the RF- form of RA.

And while the claims broadly encompass identifying altered risk of any autoimmune disease, it is relevant to point out that the post-filing art of Criswell et al (2005) indicates that the rs2476601 SNP is not significantly associated with several autoimmune diseases, for example Graves disease or multiple sclerosis (p.567, left col., lns.22-32; Table 5) where the 95% confidence interval (95% CI) of the odds ratio (OR) includes the value of 1.00 (Table 5). It is thus highly unpredictable which particular, if any, autoimmune diseases other than RF+ RA, as associated with the nucleotide content of position 101 of SEQ ID NO: 5502.

Quantity of experimentation required

A large and prohibitive amount of experimentation would have to be performed in order to make and use the claimed invention in the full scope of the claims. Such experimentation would include examining any organism and determining the association of any SNP 'as represented by a nucleotide sequence selected from the group consisting of SEQ ID NO: 5502' with any altered risk of developing any autoimmune disease. This would involve large case:control studies in multiple human populations as well as non-human populations, and the analysis of many different polymorphic variants of different nucleotide sequences and a large number of phenotypes that are considered diseases with any autoimmune component. Even if such a large analysis were to be performed, there is no guarantee that one would find any significant associations beyond those specifically taught in the particular example of the instant specification.

Conclusion

Taking into consideration the factors outlined above, including the nature of the invention and breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the lack of guidance by the applicant and the few specific working examples, it is the conclusion that an undue amount of experimentation would be required to make and use the invention in the full scope of the claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank GI 16874864 (9-Nov-2001).

GenBank GI 16874864 teaches the sequence of clone RP11-78O10 which is a portion of human chromosome 3.

Regarding claims 23 and 24, the reference teaches a sequence wherein positions 149,137-149,337 of the sequence are identical to positions 1-201 of the sequence disclosed as SEQ ID NO: 5502, where in the reference the SNP is a nucleotide content A. The reference thereby teaches a method of determining the sequence of the nucleic acid molecule RP11-78O10, wherein said method comprises detecting the presence of nucleotides 1-201 of present SEQ ID NO: 5502. The reference indicates that the sequence was determined by sequencing a clone using Dye-terminator technology (see Comment on page 1 - Chemistry), relevant to claim 24. The process of sequencing (where a nucleotide triphosphate is incorporated into a polynucleotide primer by a polymerase after the nucleotide base pairs with a complementary base on an opposite DNA strand, and the analyzed length of the strand can detect nucleotide incorporation) is a process in which a test sample is contacted

with a reagent that specifically hybridizes to a SNP, and binding of the reagent is detected (relevant to claim 23).

Conclusion

12. No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER